

JUL 5 2002

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: April 25, 2002

Submitter: Bayer Diagnostics

Address: Bayer Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
phone: (914)-524-2446

Contact: Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs

Device: Trade/Proprietary Name: CLINITEK ATLAS® PRO™ 12 Reagent
Pak System
Common/Usual Name: Reagent Strips for Urinalysis
Test for Creatinine in Urine

Document Control Number: K021428

Classification:

Name: Creatinine test system

Class: II

CFR: 21 CFR §862. 1225

Code: 75 JFY

Predicate Devices: Multistix PRO™ 11 Reagent Strips
Multistix PRO™ 10LS Reagent Strips
Multistix PRO™ 7G Reagent Strips
CLINITEK® 50, CLINITEK® 100, CLINITEK® 200+,
CLINITEK® 500 Urine Chemistry Analyzers
Manufacturer: Bayer Diagnostics

Device Description:

The CLINITEK ATLAS PRO 12 Reagent Pak is a roll of firm plastic to which are affixed 490 reagent strips. It is for use with the CLINITEK ATLAS® Automated Urine Chemistry Analyzer. Each reagent strip contains 11 separate reagent areas to test for low level protein (15 mg/dL albumin), high level protein (>30 mg/dL protein), creatinine, occult blood, glucose, ketone (acetoacetic acid), leukocytes, nitrite, pH, bilirubin and urobilinogen. A protein-to-creatinine ratio is also determined. In addition, each strip contains a nonreactive 12th pad that is used for the determination of the specimen color.

Intended Use:

The CLINITEK ATLAS PRO 12 Reagent Pak system is intended for use in at-risk patient groups to assist diagnosis in the following areas: kidney function, carbohydrate metabolism, urinary tract infections and liver function. The system also measures physical characteristics, including acid-base balance and urine concentration. Test results can be used along with other diagnostic information to rule out certain disease states. The CLINITEK ATLAS PRO 12 Reagent Pak system is for professional use in centralized laboratory locations such as in hospitals and reference laboratories.

Technological Characteristics:

The CLINITEK ATLAS PRO 12 Reagent Pak system includes a new "Protein Low" reagent that allows "low level" detection of urine albumin at 15 mg/dL in addition to the current protein reagent used for detection of "high level" protein at 30 mg/dL. A new creatinine reagent is used for the estimation of the protein-to-creatinine ratio of the urine specimen based on all three tests. Use of the protein-to-creatinine ratio can assist in the diagnosis of kidney function by minimizing the impact of changes in the protein result due to exercise, orthostatic proteinuria, diuresis and urine concentration. The ratio allows for the use of single-void specimens in the discrimination of normal and abnormal levels of protein. Ratio results of >150 mg/g are considered to be abnormal.

The assay for low level protein (albumin) is based on dye binding using the high affinity dye, Bis(3',3''-diiodo-4',4''-dihydroxy-5',5''-dinitrophenyl)-3,4,5,6-tetrabromosulfonephthalein). At a constant pH, the development of a blue color is owing to the presence of albumin; the intensity of the color is proportional to the albumin concentration. The assay for creatinine is based on the peroxidase-like activity of copper creatinine complexes that catalyze the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethyl-benzidine.

Assessment of Performance:

The performance of the CLINITEK ATLAS PRO 12 Reagent Pak System was studied internally and in clinical settings. The studies demonstrated that typical users in centralized laboratories could obtain clinical test results that are comparable to commonly used laboratory tests.

Conclusion:

The CLINITEK ATLAS PRO 12 Reagent Pak System has been developed for use with the CLINITEK ATLAS Automated Urine Chemistry Analyzer. New tests for the determination of low levels of albumin and urine creatinine have been added to the CLINITEK ATLAS Automated Urine Chemistry Analyzer menu to allow for a determination of the protein-to-creatinine ratio of the urine specimen. Studies show that the product provides clinical results comparable to other test methods in current clinical practice.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Re: k021428
Trade/Device Name: Clinitek Atlas® Pro™ 12 Reagent Pak System
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: JFY; JIP; JIL; LJX
Dated: April 25, 2002
Received: May 3, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

K021428

Device Name:

CLINITEK ATLAS® PRO™ 12 Reagent Pak System

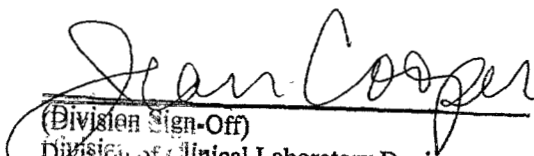
Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021428

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)